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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/016,763

10/26/2001

Ronald P. Taylor

9426-059

4486

20583

7590

06/14/2006

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,763	TAYLOR ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12232004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 08/202,572.

Claims 5 and 18 have been canceled.

Claims 1-4, 6-17 and 19 are currently pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-4, in the reply filed on April 7, 2006 is acknowledged. The traversal is on the ground(s) that it would not constitute a serious burden on the Examiner to examine both the compound and method of using the compound. This is not found persuasive because the invention of Group I can also be used for methods not related to the claimed methods of use and the claimed methods of use require different steps for their practice which do not overlap and require separate searches.

The requirement is still deemed proper and is therefore made FINAL.

2. **Claims 6-17 and 19 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 7, 2006.

Accordingly, **claims 1-4 are the subject of examination** in the present Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The hybridoma cell lines producing the antibodies "1B4, HB8592 and 7G9" are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or

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available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of said cell lines. *See 37 C.F.R. 1.802.*

The instant specification discloses that the antibodies are disclosed in non-patent literature or developed in the inventor's laboratory (page 6, line 22 to page 7, line 13 for example), but there is no disclosure of deposit of the hybridomas that produce the claimed monoclonal antibodies at any acceptable depository.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 C.F.R. 1.808.*

If the deposit has not been made under the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

In addition, the identifying information set forth in 37 C.F.R. 1.809 (d) should be present in the specification. *See 37 C.F.R. 1.803-1.809* for additional explanation of these requirements.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 C.F.R. 1.801-1.809 for further information concerning deposit practice. *See MPEP 1.804(b).*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is indefinite and ambiguous to recite the laboratory names 1B4, HB8592 and 7G9 in claim 2 to identify the antibodies. The same designations may likely to be used by others as well to designate different antibodies or cell lines. It is suggested that the corresponding accession or deposit numbers from an acceptable depository be recited in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (J. Immunol. [1992] 148(8):2462-2468; C17 on form PTO-1449 filed 12/23/04) in view of Kimberly et al (J. Clin. Invest. [1989] 84(3):962-970; C10 on form PTO-1449) and Emlen et al (J. Immunol. Meth. [1990] 132(1):91-101; C03 on form PTO-1449).

Taylor teaches the production of bispecific heteropolymers comprising an antibody to complement receptor (CR1) on primate erythrocytes. Taylor specifically teaches the monoclonal antibody 1B4 [claim 2] as a part of the heteropolymer (page 2462, column 2 in particular). Taylor teaches conjugation of 1B4 via avidin/biotin linkage to a second antibody, which is directed to an antigen of interest. Taylor further teaches the usefulness of the heteropolymer for erythrocyte-mediated clearance immune complexes in a primate (squirrel monkey) subject (Abstract in particular).

Taylor does not teach heteropolymers of anti-CR1 antibodies with an antigen that is specifically recognized by a pathogenic antibody or autoantibody.

Kimberly teaches erythrocyte-mediated clearance of dsDNA/anti-dsDNA immune complexes (Abstract in particular). Kimberly further teaches that these immune complexes “are relevant to autoimmune disease,” “have well characterized immunochemical properties” and their behavior has been studied in primates. Kimberly further teaches that the immune complexes fix complement efficiently, bind avidly to primate erythrocytes via CR1 and release slowly from human erythrocytes (page 967, column 1 in particular). Accordingly, Kimberly establishes the importance of dsDNA/anti-dsDNA complexes in autoimmunity, providing motivation for a person having ordinary skill in the art at the time the invention was made to identify methods of removing the pathogenic anti-dsDNA antibodies.

The teachings of Taylor and Kimberly do not specifically teach heteropolymers comprising anti-CR1 monoclonal antibodies and dsDNA.

Emlen teaches methods for biotinylating dsDNA in a manner suitable for attaching the biotinylated dsDNA to streptavidin. Emlen further teaches that the biotinylated dsDNA retains its immunogenicity (Abstract in particular). Accordingly, the artisan would reasonably expect that biotinylated dsDNA would be able to be bound by anti-dsDNA antibodies in the peripheral circulation of a subject having an autoimmune disease in which anti-dsDNA antibodies are a factor.

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings in order to facilitate erythrocyte-mediated removal of anti-dsDNA antibodies from the peripheral blood of primates with an autoimmune disease such as systemic lupus erythematosus (SLE). One would have been motivated to combine the teachings with a reasonable expectation of success because Taylor teaches that the use of an anti-CR1 antibody such as 1B4 would be an effective way to facilitate erythrocyte-mediated clearance of immune complexes from primates, Kimberly teaches that dsDNA/anti-dsDNA immune complexes can be cleared from a primate via erythrocyte-mediated clearance and Emlen teaches that biotinylated dsDNA retains its ability to bind pathogenic anti-dsDNA antibodies from the blood of subjects with SLE. Therefore the artisan would have reasonably expected that replacing the biotinylated second antibody of the complex taught by Taylor with the biotinylated dsDNA of Emlen would create a complex comprising an anti-CR1 antibody and an antigen specific for an a target pathogenic antibody or autoantibody that is useful for facilitating erythrocyte-mediated removal of the target pathogenic antibody or autoantibody.

Conclusion

5. No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 8, 2006




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PRIMARY EXAMINER
ART UNIT 182-1644